Atty. Dkt. No. 038602-1214

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Gregory PLOWMAN et al.

Title: NOVEL PROTEASES

Appl. No.: 09/888,615

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Examiner: Michael L. Borin

Art Unit: 1645

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

This is a response to the restriction requirement mailed on July 1, 2003. By the attached Petition for an Extension of Time, Applicants have extended the response due date until December 1, 2003. Accordingly, this response is timely.

The Office restricted the application into nine (9) groups, with each group being further divided 59-ways for each recited sequence. This amounts to a 531-way restriction requirement. The groups were defined as follows:

Group 1 Claims 1-5 and 24-26, drawn to polynucleotides encoding full-length polypeptides, analogs and fragments thereof, and vectors and transformed host cells, classified in class 536, subclass 23.1

Group 2 Claims 6-8, drawn to a purified polypeptide, classified in class 530, subclass 300

Group 3 Claims 9-11, drawn to an antibody to a polypeptide, classified in class 530, subclass 388.1

Group 4 Claim 12, drawn to a method of screening based on interaction with a polypeptide, classified in class 435, subclass 7.1

Group 5	Claim 13, drawn to a method of screening based on expression of a polypeptide, classified in class 435, subclass 7.1
Group 6	Claims 14-19, drawn to a method of treatment using a polypeptide, classified in class 514, subclass 12
Group 7	Claims 20-23, drawn to polynucleotide-based methods of screening, classified in class 435, subclass 6
Group 8	Claims 27-29, drawn to 10-30 residue long nucleotides, classified in class 536, subclass 23.1
Group 9	Claims 9-11, drawn to a method of using antibodies, classified in class 435, subclass 7.1.

Applicants hereby provisionally elect Group V and SEQ ID NO: 73 for examination, with traverse.

As a basis for traversal, Applicants submit that the Office has failed to establish a need for restriction. The criteria for a proper restriction requirement, according to MPEP § 803, are (1) that the inventions must be independent or distinct as claimed, and (2) that there must be a serious burden on the Examiner to examine the entire application. In this case, the Examiner has failed to demonstrate that a serious examination burden exists absent restriction.

Indeed, the requirement to elect a single amino acid sequence runs counter to the PTO's own policy that "up to ten (10) independent and distinct nucleotide sequences [normally] will be examined in a single application without restriction," to aid the biotechnology industry "without creating an undue burden on the Office." See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996) and MPEP 803.04. The Office has failed to articulate any justification for suspending that policy in this case. In particular, the Office has not established that the sequences in this application are any more difficult to examine than those in a "normal" biotechnology case, thereby making it unreasonable to examine more than a single sequence.

Moreover, unless the subject matter lacks unity of invention, it is improper for the Office to refuse to examine what Applicants regard as their invention. See, e.g., *In re*

Harnish, 631 F.2d 716 (CCPA 1980); *In re Weber*, 580 F.2d 455 (CCPA 1978) and *In re Haas*, 580 F.2d 461 (CCPA 1987). Unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. MPEP 803.02. In this case, the claimed polynucleotides and polypeptides share substantial structural features indicative of their common utilities. All the polypeptides have defining protease structural features. At a more detailed level, proteins encoded by SEQ ID NOs: 60-62 share structural features indicative of Zn carboxypeptidase family of carboxypeptidase proteases; proteins encoded by SEQ ID NOs: 64-77 share structural features indicative of the UCH2b family of cysteine proteases; proteins encoded by SEQ ID NOs: 78-81 share structural features indicative of metalloproteases; and proteins encoded by SEQ ID NOs: 83-118 share structural features indicative of trypsin serine proteases.

Additionally, Applicants submit that the joint examination of Groups I and II would not create an undue burden for the Office. Group I is drawn to polynucleotides and Group II is drawn to polypeptides. The search required for examination of these groups would be done in electronic databases that effortlessly convert polynucleotide sequences to polypeptide sequences. A search for Group I, therefore, easily could encompass a search of Group II.

For these reasons, Applicants respectfully request withdrawal or revision of the restriction requirement.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to

Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 12/1/03

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